

CLAIMS

1. A pharmaceutical composition for the treatment of an ear disorder in a form selected from foam and mousse comprising:
 - a. at least one pharmaceutical agent known to affect an ear disorder;
 - 5 b. a pharmaceutically acceptable carrier comprising at least one dispersing agent that is a foam forming agent;
 - c. a dispensing device adapted for the dispensing the agent of a) admixed with the agent of b) to the external auditory meatus in a form selected from a foam and a mousse.
- 10 2. The pharmaceutical composition according to claim 1 wherein the dispersing agent is selected from a surfactant, a cholesteryl ester, a fatty acid, a phospholipid, a carbohydrate and a protein.
3. The pharmaceutical composition according to claim 2 wherein the surfactant is selected from a natural ionic surfactant, a synthetic ionic surfactant, a natural non-15 ionic surfactant, a synthetic non- ionic surfactant and a mixture thereof.
4. The pharmaceutical composition according to claim 1 wherein the dispensing device is selected from an aerosol and a non-aerosol dispensing device.
5. The pharmaceutical composition according to claim 4 wherein the dispensing device is an aerosol dispensing device, further comprising an aerosol propellant.
- 20 6. The pharmaceutical composition according to claim 1 wherein said dispensing device is a metered dose dispensing device.
7. The pharmaceutical composition according to claim 1 wherein the ear disorder is a condition that requires administration of a pharmaceutical composition into the external auditory meatus of the treated subject, so as to thereby treat the subject.
- 25 8. The pharmaceutical composition according to claim 1, wherein the ear disorder is selected from an external ear disorder, a middle ear disorder and an inner ear disorder.
9. The pharmaceutical composition according to claim 8 wherein the external ear disorder is selected from otitis externa, necrotizing external otitis, otomycosis,

perichondritis, bullous myringitis, herpes zoster oticus, contact dermatitis, ear eczema, lacerations of the external canal, presence of foreign bodies, pilar (sebaceous) cysts, epidermal cysts, benign lesions including exostosis and malignant lesions including basal cell epithelioma and squamous cell carcinoma.

5 10. The pharmaceutical composition of claim 9 wherein the external ear disorder is selected from otitis externa, and acute otitis externa.

11. The pharmaceutical composition according to claim 8 wherein the middle ear disorder is selected from otitis media, chronic otitis media, serous otitis media, acute and chronic suppurative otitis media, acute and chronic mastoiditis, adenoid 10 hypertrophy, intratubal obstruction, middle ear obstruction, perforation of the tympanic membrane, cholesteatoma, tympanosclerosis, temporal bone fractures, barotrauma, glomus tumors and malignant neoplasia.

15 12. The pharmaceutical composition according to claim 11 the ear disorder is a middle ear disorder selected from acute otitis media, suppurative otitis media and mastoiditis.

13. The pharmaceutical composition of claim 1, wherein the ear disorder is otalgia induced by any physical or biological cause.

14. The pharmaceutical composition of claim 13, wherein the cause of the otalgia is selected from an allergic reaction, acute sinusitis, chronic sinusitis, a tooth abscess, 20 a sore throat with referred pain to the ear and otitis media.

15. The pharmaceutical composition according to claim 1 wherein the least one pharmaceutically active agent is selected from an antibiotic agent, an antibacterial agent, an antifungal agent, a steroid agent, an anti-inflammatory agent, a local anesthetic agent and a mixture thereof, in a therapeutically effective amount.

25 16. The pharmaceutical composition according to claim 15 wherein the antibiotic agent is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, 30 and pharmaceutically acceptable derivatives thereof.

17. The pharmaceutical composition according to claim 15 wherein the antibacterial agent is selected from zinc, acetic acid or boric acid or a mixture thereof.
18. The pharmaceutical composition according to claim 15 wherein the steroid agent is selected from the group consisting of betamethasone, betamethasone dipropionate, fluocinonide, fluocinoline acetonide, hydrocortisone, methylprednisolone, 5 clobetasol, beclomethasone, dexamethasone sodium phosphate, triamcinolone and pharmaceutically acceptable derivatives thereof.
19. The pharmaceutical composition according to claim 15 wherein the antifungal agent is selected from the group consisting of amphotericins, fluconazole, 10 flucytosine, natamycin, miconazole, ketoconazole, amphotericin B, nystatin, cromolyn, Iodoxamide, levocabastin, naphazolin, antazoline, pheniramimane and pharmaceutically acceptable derivatives thereof.
20. The pharmaceutical composition according to claim 15 wherein the anti-inflammatory agent is selected from the group consisting of non-steroidal anti-inflammatories agents (NSAID), antipyrin and pharmaceutically acceptable 15 derivatives thereof.
21. The pharmaceutical composition according to claim 15 wherein the local anesthetic agent is selected from the group consisting of benzocaine, benzyl benzoate, bupivacaine, calamine, chloroprocaine, chloroxylenol, cinchocaine, cocaine, 20 dexivacaine, diamocaine, dibucaine, dyclonine, etidocaine, hexylcaine, ketamine, levobupivacaine, lidocaine, menthol, mepivacaine, oxethazaine, phenol, pramoxine, prilocaine, amethocaine, tetracaine, proparacaine, propoxyacaine, pyrrocaine, resorcinol, risocaine, rodocaine, ropivacaine, tetracaine, , and pharmaceutically acceptable derivatives thereof.
- 25 22. The pharmaceutical composition according to claim 1 wherein the treated subject is a mammal.
23. The pharmaceutical composition according to claim 22 wherein said mammal is a human being.
24. A method of preparing a pharmaceutical composition for the treatment of an ear disorder in the form selected from a foam and mousse, the method comprising the 30 steps of:

- a. providing a pharmaceutical agent known to affect an ear disorder;
- b. admixing the pharmaceutical agent of step (a) with a suitable pharmaceutically acceptable carrier comprising a dispersing agent that is a foam forming agent;
- c. introducing the mixture of (b) into a dispensing device adapted for the dispensing the composition to the external auditory meatus in the form of a foam or mousse.

5 25. The method according to claim 24 wherein the dispersing agent is selected from a surfactant, a cholesteryl ester, a fatty acid, a phospholipid, a carbohydrate and a protein.

10 26. The method according to claim 25 wherein the surfactant is selected from a natural ionic surfactant, a synthetic ionic surfactant, a natural non-ionic surfactant, a synthetic non- ionic surfactant and a mixture thereof.

27. The method according to claim 24 wherein the dispensing device is selected from an aerosol dispensing device and a non-aerosol dispensing device.

15 28. The method according to claim 27 wherein the dispensing device is an aerosol dispensing device, further comprising an aerosol propellant.

29. The method according to claim 24 wherein said dispensing device is a metered dose dispensing device.

30. The method according to claim 24 wherein the ear disorder is a condition that 20 requires administration of a pharmaceutical composition into the external auditory meatus of the treated subject, so as to thereby treat the subject.

31. The method according to claim 24, wherein the ear disorder is selected from an external ear disorder, a middle ear disorder and an inner ear disorder.

32. The method of claim 24, wherein the ear disorder is otalgia induced by any 25 physical or biological cause.

33. The method according to claim 24 wherein the least one pharmaceutically active agent is selected from an antibiotic agent, an antibacterial agent, an antifungal agent, a steroid agent, an anti-inflammatory agent, a local anesthetic agent and a mixture thereof, in a therapeutic effective amount.

34. The method according to claim 33 wherein the antibiotic agent is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, 5 paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, and pharmaceutically acceptable derivatives thereof.

35. The method according to claim 33 wherein the antibacterial agent is selected from zinc, acetic acid or boric acid or a mixture thereof.

10 36. The method according to claim 33 wherein the steroid agent is selected from the group consisting of betamethasone, betamethasone dipropionate, fluocinonide, fluocinoline acetonide, hydrocortisone, methylprednisolone, clobetasol, beclomethasone, dexamethasone sodium phosphate, triamcinolone and pharmaceutically acceptable derivatives thereof.

15 37. The method according to claim 33 wherein the antifungal agent is selected from the group consisting of amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, amphotericin B, nystatin, cromolyn, lodoxamide, levocabastin, naphazolin, antazoline, pheniramimane and pharmaceutically acceptable derivatives thereof.

20 38. The method according to claim 33 wherein the anti-inflammatory agent is selected from the group consisting of non-steroidal anti-inflammatory agents (NSAID), antipyrin and pharmaceutically acceptable derivatives thereof.

39. The method according to claim 33 wherein the local anesthetic agent is selected from the group consisting of benzocaine, benzyl benzoate, bupivacaine, calamine, 25 chloroprocaine, chloroxylenol, cinchocaine, cocaine, dexivacaine, diamocaine, dibucaine, dyclonine, etidocaine, hexylcaine, ketamine, levobupivacaine, lidocaine, menthol, mepivacaine, oxethazaine, phenol, pramoxine, prilocaine, amethocaine, tetracaine, proparacaine, propoxycaaine, pyrrocaaine, resorcinol, risocaine, rodocaine, ropivacaine, tetracaine, , and pharmaceutically acceptable derivatives 30 thereof.

40. A method for the treatment of an ear disorder in a subject in need of such treatment, the method comprising the steps of:

- a. providing a pharmaceutical agent known to affect an ear disorder;
- b. admixing the pharmaceutical agent of step (a) together with a pharmaceutically acceptable carrier comprising a dispersing agent that is a foam forming agent;
- 5 c. introducing the mixture formulation of step (b) in a container that enables the dispersion of said mixture in a form selected from foam and mousse; and
- d. administering the formulation of step (c) to the external auditory meatus of said subject so as to thereby treat the ear disorder.

10 41. The method according to claim 40 wherein the dispersing agent is selected from a surfactant, a cholesteryl ester, a fatty acid, a phospholipid, a carbohydrate and a protein.

42. The method according to claim 41 wherein the surfactant is selected from a natural ionic surfactant, a synthetic ionic surfactant, a natural non-ionic surfactant, a 15 synthetic non- ionic surfactant and a mixture thereof.

43. The method according to claim 40 wherein the dispensing device is selected from an aerosol dispensing device and a non-aerosol dispensing device.

44. The method according to claim 43 wherein the dispensing device is an aerosol dispensing device, further comprising an aerosol propellant.

20 45. The method according to claim 40 wherein said dispensing device is a metered dose dispensing device.

46. The method according to claim 40 wherein the ear disorder is a condition that requires administration of a pharmaceutical composition into the external auditory meatus of the treated subject, so as to thereby treat the subject.

25 47. The method according to claim 46, wherein the ear disorder is selected from an external ear disorder, a middle ear disorder and an inner ear disorder.

48. The method according to claim 47 wherein the external ear disorder is selected from otitis externa, necrotizing external otitis, otomycosis, perichondritis, bullous myringitis, herpes zoster oticus, contact dermatitis, ear eczema, lacerations of the

external canal, presence of foreign bodies, pilar (sebaceous) cysts, epidermal cysts, benign lesions including exostosis and malignant lesions including basal cell epithelioma and squamous cell carcinoma.

49. The method of claim 48 wherein the external ear disorder is selected from otitis 5 externa, and acute otitis externa.

50. The method according to claim 47 wherein the middle ear disorder is selected from otitis media, chronic otitis media, serous otitis media, acute and chronic suppurative otitis media, acute and chronic mastoiditis, adenoid hypertrophy, intratubal obstruction, middle ear obstruction, perforation of the tympanic 10 membrane, cholesteatoma, tympanosclerosis, temporal bone fractures, barotrauma, glomus tumors and malignant neoplasia.

51. The method according to claim 50 the ear disorder is a middle ear disorder selected from acute otitis media, suppurative otitis media and mastoiditis.

52. The method of claim 40, wherein the ear disorder is otalgia induced by any 15 physical or biological cause.

53. The method of claim 52, wherein the cause of the otalgia is selected from an allergic reaction, acute sinusitis, chronic sinusitis, a tooth abscess, a sore throat with referred pain to the ear and otitis media.

54. The method according to claim 40 wherein the least one pharmaceutically active 20 agent is selected from an antibiotic agent, an antibacterial agent, an antifungal agent, a steroid agent, an anti-inflammatory agent, a local anesthetic agent and a mixture thereof, in a therapeutic effective amount.

55. The method according to claim 54 wherein the antibiotic agent is selected from the 25 group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, and pharmaceutically acceptable derivatives thereof.

56. The method according to claim 54 wherein the antibacterial agent is selected from zinc, acetic acid or boric acid or a mixture thereof.
57. The method according to claim 54 wherein the steroid agent is selected from the group consisting of betamethasone, betamethasone dipropionate, fluocinonide, fluocinoline acetonide, hydrocortisone, methylprednisolone, clobetasol, beclomethasone, dexamethasone sodium phosphate, triamcinolone and pharmaceutically acceptable derivatives thereof.
- 10 58. The method according to claim 54 wherein the antifungal agent is selected from the group consisting of amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, amphotericin B, nystatin, cromolyn, lodoxamide, levocabastin, naphazolin, antazoline, pheniramimane and pharmaceutically acceptable derivatives thereof.
- 15 59. The method according to claim 54 wherein the anti-inflammatory agent is selected from the group consisting of non-steroidal anti-inflammatory agents (NSAID), antipyrin and pharmaceutically acceptable derivatives thereof.
- 20 60. The method according to claim 54 wherein the local anesthetic agent is selected from the group consisting of benzocaine, benzyl benzoate, bupivacaine, calamine, chloroprocaine, chloroxylenol, cinchocaine, cocaine, dexivacaine, diamocaine, dibucaine, dyclonine, etidocaine, hexylcaine, ketamine, levobupivacaine, lidocaine, menthol, mepivacaine, oxethazaine, phenol, pramoxine, prilocaine, amethocaine, tetracaine, proparacaine, propoxycaine, pyrrocaine, resorcinol, risocaine, rodocaine, ropivacaine, tetracaine and pharmaceutically acceptable derivatives thereof.
61. The method according to claim 40 wherein the treated subject is a mammal.
- 25 62. The method according to claim 61 wherein said mammal is a human being.
63. Use of a pharmaceutical composition in a form selected from a foam and a mousse for the treatment of any ear disorder which requires administration of a pharmaceutical composition through the external auditory meatus of a treated subject, so as to thereby treat the ear disorder.